

EXHIBIT 5A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ROBIN ROBERTS, and SAMUEL CISNEROS,
Individually and on behalf of all others similarly
situated,

Plaintiffs,

v.

TORRENT PHARMA, INC.;
-and-
TORRENT PHARMACEUTICALS LIMITED;
-and-
HUHAI, U.S. INC.;
-and-
ZHEJIANG HUAHAI PHARMACEUTICAL CO.,
LTD.;

Defendants.

Civil Action No. 1:18cv16075

Jury Trial Demanded
Complaint-Class Action

CLASS ACTION COMPLAINT

Plaintiffs Robin Roberts and Samuel Cisneros (“Plaintiffs”), individually and on behalf of all others similarly situated, bring this action against Torrent Pharma, Inc. (“Torrent Pharma”), Torrent Pharmaceuticals Limited (“Torrent Limited”), Huahai U.S. Inc. (“Huahai U.S.”), and Zhejiang Huahai Pharmaceutical Co., Ltd. (“ZHP”). Plaintiffs’ allegations are based upon personal knowledge, the investigation of counsel, and information and belief.

I. INTRODUCTION

1. Plaintiffs brings this action on behalf of themselves and hundreds of thousands of other Valsartan consumers who paid for Defendants’ generic Valsartan that was adulterated through its contamination with an IARC- and EPA-listed probable human carcinogen known as N-nitrosodimethylamine (“NDMA”).

2. At all times during the period alleged herein, Defendants represented and warranted to consumers that their generic Valsartan products were therapeutically equivalent to and otherwise the same as brand DIOVAN®, were otherwise fit for their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

3. However, for years, Defendants willfully ignored warnings signs regarding the operating standards at the Zhejiang Huahai Pharmaceuticals (“ZHP”) manufacturing plant in China, and continued to allow ZHP to manufacture their Valsartan products for sale to consumers in the United States even after Defendants knew or should have known that their Valsartan products manufactured by ZHP contained or likely contained NDMA and/or other impurities.

4. These adulterated Valsartan drugs were introduced into the American market at least as far back as 2015 for Defendants to profit from their sale to American consumers, such as Plaintiffs and Class Members. However, evidence now suggests that the contamination dates back at least as far as 2012. Plaintiffs and Class Members paid for all or part of their Valsartan prescriptions that were illegally introduced into the market by Defendants and which were not fit for their ordinary use. Defendants have been unjustly enriched through the sale of these adulterated drugs since at least 2012. Defendants’ conduct also constitutes actionable common law fraud, consumer fraud, and other violations of state law.

II. PARTIES

5. Plaintiff Robin Roberts is a citizen and resident of Virginia, who resides and is domiciled in Mechanicsville, Virginia. During the class period, Plaintiff paid money for one or more of Defendants’ Valsartan products. Defendants expressly and impliedly warranted to Plaintiff Roberts that their respective generic Valsartan products were the same as brand Diovan. Had Defendants’ deception about the impurities within their products been made known earlier, Plaintiff Roberts would not have paid for Defendants’ Valsartan products.

6. Plaintiff Samuel Cisneros is a citizen and resident of Texas, who resides and is domiciled in Houston, Texas. During the class period, Plaintiff paid money for one or more of the Defendants' Valsartan products. Defendants expressly and impliedly warranted to Plaintiff Cisneros that their respective generic Valsartan products were the same as brand Diovan. Had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Cisneros would not have paid for Defendants' Valsartan products.

7. Defendant Torrent Pharma, Inc. ("Torrent Pharma") is a Delaware corporation with its principal place of business in New Jersey located at 150 Allen Road, Basking Ridge, New Jersey 07920. At all times material to this case, Torrent Pharma has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States, including in the States of Virginia and New Jersey.

8. Defendant Torrent Pharmaceutical Limited ("Torrent Limited") is an Indian company with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad – 380009, Gujara, India. On information and belief, Torrent Limited exercised control over subsidiary and/or affiliate entities that sold generic Valsartan in the United States, including but not limited to Torrent Pharma. At all times materials to this case, Torrent Limited engaged in the manufacturing, sale, and/or distribution of adulterated generic Valsartan in the United States, including in the States of Virginia and New Jersey, and purposefully availed itself of doing business in the United States and New Jersey

9. Defendant Huahai U.S. Inc. ("Huahai U.S.") is a New Jersey corporation, with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Defendant Huahai U.S. is a subsidiary of ZHP (see below). At all times material to this case, Huahai has been engaged in the manufacture, sale, and distribution of adulterated generic Valsartan in the United States, including in the States of Virginia and New Jersey.

10. Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. (“ZHP”) is a Chinese company, organized under the laws of China, with its principal place of business located at Coastal Industrial Zone, Chuannan No. 1 Branch, Linhai, Zhejiang Province 317016 China. On information and belief, ZHP exercised control over subsidiary and/or affiliate entities that sold generic Valsartan in the United States, including but not limited to Prinston, Solco U.S., and Huahai U.S. At all times materials to this case, ZHP engaged in the manufacturing, sale, and/or distribution of adulterated generic Valsartan in the United States, including in the States of Virginia and New Jersey, and purposefully availed itself of doing business in the United States and New Jersey.

III. JURISDICTION AND VENUE

11. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendants, (b) the amount in controversy exceeds \$5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action. In addition, this Court has original jurisdiction pursuant to 28 U.S.C. § 1331.

12. This Court has personal jurisdiction over Defendants because Defendants have sufficient minimum contacts in Virginia, Texas and New Jersey (and the United States generally), and otherwise intentionally avails themselves of the markets within these states through its business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

13. Venue is proper in this District because “a substantial part of the events or omissions” giving rise to the class claims occurred in this District, 28 U.S.C. § 1391(b)(2); and because Defendants are subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

IV. FACTUAL ALLEGATIONS

A. Valsartan Background

14. Valsartan is a potent, orally active nonpeptide tetrazole derivative which cases a reduction in blood pressure, and is used in the treatment of hypertension, heart failure, and post-myocardial infarction.

15. Valsartan is the generic version of the registered listed drug (“RLD”) DIOVAN® (“Diovan”), which was marked in tablet form by Novartis AG (“Novartis”) beginning in July 2001 upon approval by the U.S. Food and Drug Administration (“FDA”).

16. Diovan was an immensely popular drug. Globally, Diovan generated \$5.6 billion in sales in 2011 according to Novartis’s Form 20-F for that year, of which \$2.33 billion was from the United States.

17. Diovan’s FDA-approved label specifies its active and inactive ingredients. NDMA is not an FDA-approved ingredient of Diovan. Nor is NDMA an FDA-approved ingredient of any generic Valsartan product.

18. Although Novartis’s Diovan patents expired in September 2012, Novartis was spared generic competition until approximately June 2014 because Ranbaxy Pharmaceuticals (the generic exclusivity holder) was unable to achieve FDA approval for its generic Diovan, thus effectively preventing other generic competition under the Hatch-Waxman Act, until Ranbaxy achieved FDA approval and began to market its generic product.

B. The Generic Drug Approval Framework

19. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

20. Brand drug companies submitting a New Drug Application (“NDA”) are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

21. By contrast, generic drug companies submit an Abbreviated New Drug Application (“ANDA”). Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug (“RLD”). Bioequivalence is the “absence of significant difference” in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

22. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two drug products is accepted as ~~as~~ ~~as~~ evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

23. In other words, generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is “bioequivalent” to the RLD and “can be expected to have the same therapeutic effect,” *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make “a full statement of the composition of such drug” to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C).

24. And finally, a generic manufacturer must also submit information to show that the “labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]” 21 U.S.C. § 355(j)(2)(A)(v).

25. Upon granting final approval for a generic drug, the FDA will typically state the generic drug is “therapeutically equivalent” to the branded drug. The FDA codes generic drugs as

“A/B rated” to the RLD branded drug. Pharmacists, physicians, and patients can fully expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the same labeling as the RLD delivered to consumers in each and every prescription of its generic products.

26. According to the FDA, there are fifteen Abbreviated New Drug Applications (“ANDAs”) approved for generic Diovan, *i.e.*, Valsartan.

C. Background on Current Good Manufacturing Practices (“cGMPs”)

27. Under federal law, pharmaceutical drugs must be manufactured in accordance with “current Good Manufacturing Practices” (“cGMPs”) to assure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

28. The FDA’s cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K).

The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

29. Any drug not manufactured in accordance with cGMPs is deemed “adulterated” and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). Drugs are deemed to be adulterated if the manufacturer fails to comply with cGMPs to assure the drugs’ safety, quality, purity, identity, and strength and/or if they are contaminated. *See* 21 U.S.C. § 351(a)(2)(A), (B). Federal law prohibits a manufacturer from directly or indirectly causing adulterated drugs to be introduced or delivered for introduction into interstate commerce. *See id.*

§ 331(a). States have enacting laws adopting or mirroring these federal standards.

30. Per federal law, cGMPs include “the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.” 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors’ operations.

31. Indeed FDA regulations require a “quality control unit” to independently test drug product manufactured by another company on contract:

(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

21 C.F.R. § 211.22(a).

D. ZHP Manufacturing Facilities

32. ZHP is the corporate owner, director, or parent of Defendants Prinston, Huahai U.S., and Solco U.S., as well as other subsidiaries or affiliates involved in the manufacture, sale, and distribution of generic Valsartan. ZHP has Active Pharmaceutical Ingredient (“API”) manufacturing facilities is located in Linhai City, Zhejiang Province, China. According to ZHP’s website, ZHP was one of the first Chinese companies approved to sell generic drugs in the United States, and it remains one of China’s largest exporters of pharmaceuticals to the United States and European Union.

33. ZHP serves as a contract manufacturer of Defendants’ Valsartan products, and

Defendants thus have a quality assurance obligation with respect to ZHP's processes and finished products as set forth above pursuant to federal law.

34. ZHP has a history of deviations from FDA's cGMP standards that began almost as soon as ZHP was approved to export pharmaceuticals to the United States.

35. On or about March 27-30, 2007, the FDA inspected ZHP's Linhai City facilities.

That inspection revealed "deviations from current good manufacturing processes (cGMP)" at the  facility. Those deviations supposedly were later corrected by ZHP. The results of the inspection and the steps purportedly taken subsequent to it were not made fully available to the public. 

36. On May 15-19, 2017, FDA again inspected ZHP's Linhai City facilities. That inspection resulted the FDA's finding that ZHP repeatedly re-tested out of specification ("OOS") samples until obtaining a desirable result. This practice allegedly dated back to at least September 2016 per the FDA's letter at the time. The May 2017 inspection also resulted in FDA's finding that "impurities occurring during analytical testing are not consistently documented/quantitated[.]" These findings were not made fully available to the public.

37. Furthermore, for OOS sampling results, ZHP routinely invalidated these results without conducting any kind of scientific investigation into the reasons behind the OOS sample result.  In fact, in one documented instance, the OOS result was attributed to "pollution" in the environment surrounding the facility. These are disturbing signs of systematic data manipulation designed to intentionally conceal and recklessly disregard the presence of harmful impurities such as NDMA.

38. The May 2017 inspection also found that ZHP's "facilities and equipment [were] not maintained to ensure [the] quality of drug product" manufactured at the facility. These issues included the FDA's finding that: equipment that was rusting and rust was being deposited into drug product; equipment was shedding cracking paint into drug product; there was an

accumulation of white particulate matter; and black metallic particles found in API batches.

• **E. Defendants Were Aware of Potential NDMA Contamination As Early As 2012**

39. Upon information and belief, ZHP changed its Valsartan manufacturing processes in or about 2012, if not earlier.

40. According to the European Medicines Agency (“EMA”) – which has similar jurisdiction to that of the FDA – “NDMA was an unexpected impurity believed to have formed ~~as~~ as a side product after Zhejiang Huahai introduced changes to its manufacturing process in 2012.”¹

41. NDMA is yellow, oily liquid with a faint, characteristic odor and a sweet taste, and is often produced as a by-product of industrial manufacturing processes.

42. The World Health Organization’s (“WHO”) International Agency for Research on Cancer (“IARC”) classifies NDMA as one of sixty-six (66) agents that are “probably carcinogenic to humans” (Classification 2A).

43. The U.S. Environmental Protection Agency has likewise classified NDMA as a probable human carcinogen by giving it a “B2” rating, meaning that it is “probably carcinogenic to humans” with little or no human data.

44. Anecdotally, NDMA has also been used in intentional poisonings.²

45. Most assuredly, NDMA is not an FDA-approved ingredient for branded Diovan or generic Valsartan. None of Defendants’ Valsartan products (or any Valsartan product, for that matter) identifies NDMA as an ingredient on the products’ labels or elsewhere.

46. If Defendants had not routinely disregarded the FDA’s cGMPs and deliberately

¹ See European Medicines Agency, UPDATE ON REVIEW OF RECALLED VALSARTAN MEDICINES, at http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/detail_003000.jsp&mid=WC0b01ac058004d5c1 (last accessed Aug. 31, 2018).

² See Quartz, A COMMON BLOOD-PRESSURE MEDICINE IS BEING RECALLED BECAUSE OF A TOXIC INGREDIENT, <https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/> (last accessed Aug. 31, 2018).

manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have found the NDMA contamination almost immediately.

47. 21 C.F.R. § 211.110 contains the cGMPs regarding the “Sampling and testing of in-process materials and drug products[.]” Subsection (c) states the following:

In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

21 C.F.R. § 211.110(c).

48. And as reproduced above, Defendants’ own quality control unit are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by ZHP.

49. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants and ZHP, the NDMA contamination in Defendants’ Valsartan products would have been discovered in 2012. Defendants were thus on (at minimum) constructive notice that their Valsartan products were adulterated as early as 2012.

50. However, there are indications that Defendants and ZHP had actual knowledge of Valsartan’s contamination with NDMA, and made efforts to conceal or destroy the evidence.

51. As alleged above, FDA investigators visited ZHP’s facilities in May 2017. In the words of FDA inspectors, ZHP “invalidat[ed] [OOS] results [without] scientific justification” and did not implement “appropriate controls … to ensure the integrity of analytical testing” and routinely disregarded sampling anomalies suggestive of impurities.

52. These discoveries by the FDA’s investigators suggest that ZHP and Defendants were specifically aware of impurities in the drugs being manufactured by ZHP, including specifically contamination of Defendants’ Valsartan with NDMA. The efforts to manipulate data

constituted an explicit effort to conceal and destroy evidence and to willfully and recklessly introduce adulterated Valsartan into the U.S. market.

53. Defendants were also specifically aware of the manufacturing issues at ZHP based on Defendants' awareness of cGMP violations as early as 2012 based on their own monitoring of ZHP and of the Valsartan products being manufactured at ZHP, and based on the FDA's inspections of ZHP's facilities in March 2007 and May 2017.

54. Indeed, Defendants Solco and ZHP (as well as Huahai U.S.) are all corporate affiliates, and Solco should be imputed with actual knowledge of ZHP's willful deviations from cGMPs. Solco and Huahai U.S. have offices in the same office building in Cranbury, New Jersey.

55. And yet, Defendants knowingly, recklessly, and/or negligently introduced adulterated Valsartan into the U.S. market that was contaminated with NDMA. Defendants failed to recall their generic Valsartan products because they feared permanently ceding market share to competitors. And, upon information and belief, Defendants issued the "voluntary" recall of their Valsartan products only after the FDA had threatened an involuntary recall.

F. FDA Announces Voluntary Recall of Defendants' Adulterated Valsartan

56. On or about July 13, 2018, the FDA announced voluntary recalls by Defendants and other manufacturers for their Valsartan products manufactured by ZHP.³ The recall is for products distributed as early as October 2015. However, as alleged above, it is likely that Defendants' Valsartan manufactured 2012 and beyond was also contaminated with NDMA.

57. On or about July 27, 2018, the FDA announced expanded recalls of additional Valsartan products manufactured by Defendants and non-parties, and re-packaged by third

³ FDA News Release, FDA ANNOUNCES VOLUNTARY RECALL OF SEVERAL MEDICINES CONTAINING VALSARTAN FOLLOWING DETECTION OF IMPURITY, at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm> (last accessed Aug. 31, 2018).

parties.⁴

58. As stated in the FDA's July 13, 2018 statement:

The U.S. Food and Drug Administration is alerting health care professionals and patients of a voluntary recall of several drug products containing the active ingredient valsartan, used to treat high blood pressure and heart failure. This recall is due to an impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled products. However, not all products containing valsartan are being recalled. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured.

G. FDA Expands Its Recall to Torrent Products

59. Torrent Pharma and Torrent Limited used ZHP's facility discussed above for its own supply of certain Valsartan products which they distributed and sold in the United States.

60. Additionally, on or about August 17, 2018, Defendant Torrent Pharma and Torrent Limited issued a voluntary recall of fourteen (14) lots of Valsartan/Amlodipine/HCTZ tablets "to the consumer level due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient ('API') manufactured by Zhejiang Huahai Pharmaceuticals. The impurity detected in the API is Nnitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification."⁵

61. Torrent Pharma and Torrent Limited failed to promptly recall its products for over a month after the initial recall was announced. They did so despite knowing that their Valsartan

⁴ FDA News Release, FDA UPDATES ON VALSARTAN RECALLS, at <https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm> (last accessed Aug. 31, 2018).

⁵ FDA News Release, TORRENT PHARMACEUTICALS LIMITED ISSUES VOLUNTARY NATIONWIDE RECAL OF VALSARTAN / AMLODIPINE / HCTZ TABLETS, at <https://www.fda.gov/Safety/Recalls/ucm617347.htm> (last accessed Nov. 12, 2018).

products were sourced from ZHP.

62. On September 14, 2018, CNN reported that the FDA has found yet another cancer-causing impurity in three of the recalled lots of Torrent's valsartan-containing medications. CNN was reporting on a September 13, 2018 press release from the FDA, which indicated that "[t]his second impurity, N-Nitrosodiethylamine (NDEA) is a known animal and suspected human carcinogen. These Torrent products were included in the company's recall on August 23, 2018."⁶ Thus, in the span of two weeks, two cancer-causing impurities were found in certain lots of Torrent's valsartan-containing products.

63. Like NDMA, NDEA is acutely toxic when consumed orally.

64. Torrent Pharma's and Torrent Limited's valsartan products are neither safe nor of equal quality to the brand-name version of the medication. Additionally, "[t]he FDA and the European Medicines Agency have learned that Zhejiang Huahai Pharmaceuticals (ZHP) found NDEA in several batches of its valsartan API. The FDA immediately began retesting all valsartan API and products, including both recalled products and those currently marketed in the United States, for NDEA. Based on FDA testing to date, the agency discovered NDEA in some of ZHP's valsartan API. This impurity was also found in Torrent's valsartan 160mg (lot BV47D001) and 320mg (lots BV48D001 and BV48D002) tablets, which were made using API from ZHP and were part of the earlier recall."⁷

⁶ CNN, FDA FINDS ANOTHER IMPURITY IN RECALLED HEART DRUG, at <https://www.cnn.com/2018/09/13/health/valsartan-recall-additional-impurity-fda/index.html> (last accessed Nov. 12, 2018).

⁷ FDA, FDA PROVIDES UPDATE ON ITS ONGOING INVESTIGATION INTO VALSARTAN PRODUCTS; AND REPORTS ON THE FINDING OF AN ADDITIONAL IMPURITY IN ONE FIRM'S ALREADY RECALLED PRODUCTS, at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620499.htm> (last accessed Nov. 12, 2018).

H. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their Generic Valsartan Products

65. Each Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about their adulterated Valsartan products.

66. The FDA maintains a list of “Approved Drug Products with Therapeutic Equivalence Evaluations” commonly referred to as the Orange Book.⁸ The Orange Book is a public document; Defendants sought and received the inclusion of their products in the Orange Book upon approval of their Valsartan ANDAs. In securing FDA approval to market generic Valsartan in the United States as an Orange Book-listed therapeutic equivalent to Diovan, Defendants were required to demonstrate that their generic Valsartan products were bioequivalent to brand Diovan.

67. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA’s Orange Book, therapeutic equivalence depends in part on the manufacturer’s continued compliance with cGMPs.

68. By introducing their respective Valsartan products into the United States market under the name “Valsartan” as a therapeutic equivalent to Diovan and with the FDA-approved label that is the same as that of Diovan, Defendants represent and warrant to end users that their products are in fact the same as and are therapeutically interchangeable with Diovan.

69. Each Defendant’s Valsartan product is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved Valsartan label, Defendants, as generic manufacturers of Valsartan, made representations and express or implied warranties to consumers

⁸ FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) SHORT DESCRIPTION, at <https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeutic equivalenceevaluationsorangebook/default.htm> (last accessed Aug. 31, 2018).

of the “sameness” of their products to Diovan, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated.

70. In addition, on information and belief, each Defendant affirmatively misrepresented and warranted to consumers through their websites, brochures, and other marketing  or informational materials that their Valsartan product complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products’ FDA-approved labels.

71.  The presence of NDMA (or NDEA) in Defendants’ Valsartan: (1) renders Defendants’ Valsartan products non-bioequivalent (*i.e.*, not the same) to Diovan and thus non-therapeutically interchangeable with Diovan, thus breaching Defendants’ express warranties of sameness; (2) was the result gross deviations from cGMPs thus rendering Defendants’ Valsartan products non-therapeutically equivalent to Diovan, thus breaching Defendants’ express warranties of sameness; and (3) results in Defendants’ Valsartan containing an ingredient that is not also contained in Diovan, also breaching Defendants’ express warranty of sameness (and express warranty that the products contained the ingredients listed on each Defendant’s FDA-approved label). Each Defendant willfully, recklessly, and/or negligently failed to ensure their Valsartan products’ labels and other advertising or marketing statements accurately conveyed information about their products.

72. At all relevant times, Defendants have also impliedly warranted that their Valsartan products were merchantable and/or fit for their ordinary purposes.

73. Naturally, due to its status as a probable human carcinogen as listed by both the IARC and the U.S. EPA, NDMA (or NDEA) is not an FDA-approved ingredient in Valsartan. The presence of NDMA (or NDEA) in Defendants’ Valsartan means that Defendants have violated

implied warranties to Plaintiffs and Class Members. The presence of NDMA (or NDEA) in Defendants' Valsartan results in Defendants' Valsartan products being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of Diovan), breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

74.  For these and other reasons, Defendants' Valsartan is therefore adulterated it was illegal for Defendants' to have introduced such Valsartan in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B).

75. Adulterated Valsartan is essentially worthless. No consumer would purchase an adulterated Valsartan product or is even allowed to purchase adulterated Valsartan product because it was illegally introduced into the United States. This is especially so given that alternative, non-adulterated Valsartan products or competing medications with the same approved indications were available from other manufacturers.

I. New Revelations Continue to Unfold About Other Manufacturing Plants

76.  The recall of Defendants' Valsartan products is only the tip of the iceberg. Just two weeks after the FDA's initial recall announcement, the FDA issued another announcement expanding the recall to other Valsartan product manufactured at another plant in India, and by other non-parties. On August 20, 2018 the FDA announced that it was going to test all Valsartan products for NDMA.⁹ Additionally, on October 30, 2018, the FDA announced a voluntary recall of irbesartan products, which is a product in the same drug class as Valsartan.¹⁰ Because of Defendants' and non-parties' ongoing fraud and deception, the full scope of Defendants' and non-parties' unlawful conduct is not yet known.

 ⁹ FDA Statement, STATEMENT FROM FDA COMMISSIONER, *at* <http://freepdfhosting.com/1c7e5ed26e.pdf> (last accessed Aug. 31, 2018).

¹⁰FDA, FDA ALERTS PATIENTS AND HEALTH CARE PROFESSIONALS TO SCIEGEN'S IRBESARTAN RECALL DUE TO NDEA, *at* <https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm> (last accessed Nov. 6, 2018).

J. Fraudulent Concealment and Tolling

77. Plaintiffs and Class Members causes of action accrued on the date the FDA announced the recall of Defendants' generic Valsartan products.

78. ^x Alternatively, any statute of limitation or prescriptive period is equitably tolled on account of fraudulent concealment. Defendants each affirmatively concealed from Plaintiffs and other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge of ZHP's cGMP violations with respect to Valsartan, and of the fact that their Valsartan products were adulterated and contaminated with NMDA, and were not the same as brand Diovan.

79. For instance, no Defendant revealed to the public that their Valsartan product contained NDMA or was otherwise adulterated or non-therapeutically equivalent to Diovan until the FDA's recall announcement in July 2018. The inspection report which preceded the recall announcement was heavily redacted (including the names of the drugs affected by ZHP's cGMP violations), and prior inspection reports or warnings were not fully available to the public, if at all.

80. To the contrary, each Defendant continued to represent and warrant that their generic Valsartan products were the same as and therapeutically interchangeable with Diovan.

81. For instance, Torrent Limited maintains: "At Torrent, we strongly believe in providing quality medicines at affordable price to the patients. In this quest, primarily, we have inclined ourselves towards safeguarding both the qualitative and quantitative aspects with the help of our robust manufacturing technologies and manufacturing facilities."¹¹ Nevertheless, it did not reveal its NDMA and NDEA contamination issues in a timely fashion.

82. Because of this, Plaintiffs and other Class Members did not discover, nor would they discover through reasonable and ordinarily diligence, each Defendant's deceptive, fraudulent,

¹¹ Torrent Pharmaceuticals Limited, TORRENT PHARMA – MANUFACTURING, at <http://www.torrentpharma.com/Index.php/site/info/manufacturing> (last accessed Nov. 12, 2018).

and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations, lulled Plaintiffs and Class Members into believing that the prices paid for Valsartan were appropriate for what they believed to be non-adulterated drugs despite their exercise of reasonable and ordinary diligence.

83. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiffs and other Class Members has been tolled. Plaintiffs and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiffs were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

K. Plaintiff Robin Roberts Individual Facts

84. Plaintiff Robin Roberts is a citizen and resident of Virginia, who resides and is domiciled in Mechanicsville, Virginia.

85. On or about September 12, 2017, Plaintiff Roberts purchased generic amlodipine / valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$26.86.

86. On or about September 26, 2017, Plaintiff Roberts purchased generic amlodipine / valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$35.80.

87. On or about November 1, 2017, Plaintiff Roberts purchased generic amlodipine / valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$20.90.

88. On or about November 8, 2017, Plaintiff Roberts purchased generic amlodipine /

valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$20.90.

89. On or about November 15, 2017, Plaintiff Roberts purchased generic amlodipine / valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$23.88.

90. On or about December 2, 2017, Plaintiff Roberts purchased generic amlodipine / valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$13.72.

91. On or about December 5, 2017, Plaintiff Roberts purchased generic amlodipine / valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$35.25.

92. On or about December 15, 2017, Plaintiff Roberts purchased generic amlodipine / valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$17.57.

93. On or about December 19, 2017, Plaintiff Roberts purchased generic amlodipine / valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$22.62.

94. On or about January 24, 2018, Plaintiff Roberts purchased generic amlodipine / valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$6.26.

95. On or about March 7, 2018, Plaintiff Roberts purchased generic amlodipine / valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$6.26.

96. On or about April 20, 2018, Plaintiff Roberts purchased generic amlodipine /

valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$6.26.

97. On or about June 5, 2018, Plaintiff Roberts purchased generic amlodipine / valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$6.26.

98. ^x On or about July 8, 2018, Plaintiff Roberts purchased generic amlodipine / valsartan manufactured by Defendants and bearing NDC Number 13668-0204-30. On this occasion, Plaintiff Roberts paid a co-pay of \$6.26.

99. The generic Valsartan purchased by Plaintiff Roberts manufactured by Defendants was not therapeutically equivalent to brand Diovan, was manufactured out of compliance with cGMPs, and was adulterated by its contamination with NDMA or NDEA.

100. Defendants' generic Valsartan was sold illegally to Plaintiff Roberts.

L. Plaintiff Samuel Cisneros's Individual Facts

101. Plaintiff Samuel Cisneros is a citizen and resident of Texas, who resides and is domiciled in Houston, Texas.

102. On or about February 6, 2015, Plaintiff Cisneros purchased generic valsartan manufactured by Defendants and bearing NDC Number 13668-0070-90. On this occasion, Plaintiff Cisneros paid a co-pay of \$15.74.

103. On or about March 21, 2015, Plaintiff Cisneros purchased generic valsartan manufactured by Defendants and bearing NDC Number 13668-0070-90. On this occasion, Plaintiff Cisneros paid a co-pay of \$15.74.

104. The generic Valsartan purchased by Plaintiff Cisneros manufactured by Defendants was not therapeutically equivalent to brand Diovan, was manufactured out of compliance with cGMPs, and was adulterated by its contamination with NDMA or NDEA.

105. Defendants' generic Valsartan was sold illegally to Plaintiff Cisneros.

V. CLASS ACTION ALLEGATIONS

106. Plaintiffs bring this action both individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) against Defendants on their own behalf and on behalf of the Nationwide Class defined below:

All individuals in the United States of America and its territories and possessions who, since at least January 1, 2012, paid any amount of money out of pocket (for personal or household use) for Valsartan product manufactured by or for Defendants.

107. In the alternative, Plaintiffs allege sub-classes for all individuals in each State, territory, or possession (including specifically Virginia and New Jersey) who, since at least January 1, 2012, paid any amount of money out of pocket for Valsartan product manufactured by or for Defendants. Collectively, the foregoing Nationwide Class and alternative state sub-classes are referred to as the "Class."

108. Excluded from the Class are: (a) any Judge or Magistrate presiding over this action, and members of their families; (b) Defendants and affiliated entities, and their employees, officers, directors, and agents; (c) Defendants' legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

109. Plaintiffs reserve the right to narrow or expand the foregoing class definition, or to create subclasses as the Court deems necessary.

110. Plaintiffs meet the prerequisites of Rule 23(a) to bring this action on behalf of the Class.

111. **Numerosity:** While the exact number of Class Members cannot be determined without discovery, they are believed to consist of potentially millions of Valsartan consumers nationwide. The Class Members are therefore so numerous that joinder of all members is

impracticable.

112. Commonality: Common questions of law and fact exist as to all Class Members, including but not limited to:

- a. Whether each Defendant made express or implied warranties of “sameness” to Plaintiffs and Class Members regarding their generic Valsartan products;
- b. Whether each Defendant’s Valsartan product was in fact the same as brand Diovan consistent with such express or implied warranties;
- c. Whether each Defendant’s Valsartan product was contaminated with NDMA;
- d. Whether each Defendant’s Valsartan product containing NMDA was adulterated;
- e. Whether Defendants violated cGMPs regarding the manufacture of their Valsartan products;
- f. Whether each Defendant affirmatively misrepresented or omitted facts that its Valsartan product was the same as brand Diovan and thus therapeutically interchangeable;
- g. Whether each Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs and/or was not adulterated;
- h. Whether Plaintiffs and other Class Members have been injured as a result of each Defendant’s unlawful conduct, and the amount of damages;
- i. Whether a common damages model can calculate damages on a classwide basis;
- j. When Plaintiffs’ and Class Members’ causes of action accrued;
- k. Whether Defendants fraudulently concealed Plaintiffs’ and Class Members’ causes of action.

113. Typicality: Plaintiffs’ claims are typical of Class Members’ claims. Plaintiffs and Class Members all suffered the same type of economic harm. Plaintiffs have substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set

of facts and conduct as all other Class Members.

114. **Adequacy of Representation:** Plaintiffs are committed to pursuing this action and have retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class action, and federal court litigation. Accordingly, Plaintiffs and their counsel will fairly and adequately protect the interests of Class Members. Plaintiffs' claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiffs have no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

115. The elements of Rule 23(b)(2) are met. Defendants have acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.

116. The elements of Rule 23(b)(3) are met. Here, the common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and a class action is the superior method for fair and efficient adjudication of the controversy.

Although many other Class Members have claims against Defendants, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues is furthermore not efficient, timely or proper. Judicial resources will be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated Plaintiffs. Plaintiffs' counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the management of this case as a class action.

FIRST CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES
(INDIVIDUALLY AND ON BEHALF OF THE CLASS) 

117. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

118.  Defendants expressly warranted that its Valsartan product was fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically to and interchangeable with brand Diovan. In other words, Defendants expressly warranted that their products were the same as Diovan.

119. Defendants sold Valsartan product that they expressly warranted were compliant with cGMP and/or not adulterated.

120.  Defendants' Valsartan product did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and/or was adulterated.

121. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala.  Code § 7-2-313; Alaska Stat.  § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-

A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

122. At the time that Defendants marketed and sold its Valsartan product, they recognized the purposes for which the products would be used, and expressly warranted the products were the same as brand Diovan, and cGMP compliant and/or not adulterated. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs and other Class Members.

123. Defendants breached its express warranties with respect to its Valsartan product as it was not of merchantable quality, was not fit for its ordinary purpose, and did not comply with cGMP and/or was adulterated.

124. As a direct and proximate result of each Defendants' breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' Valsartan product they purchased was so inherently flawed, unfit, or unmerchantable as to have essentially zero, significantly diminished, or no intrinsic market value.

SECOND CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND
FITNESS
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

125. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

126. At all times relevant all fifty States and the District of Columbia and Puerto Rico

have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314;  Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

127. Defendants were a merchant within the meaning of the above statutes.

128. Defendants' Valsartan product constituted "goods" or the equivalent within the meaning of the above statutes.

129. Defendants were obligated to provide Plaintiffs and other Class Members reasonably fit Valsartan product for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

130. Defendants knew or should have known that its Valsartan product was being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to brand Diovan, and impliedly warranted that same was of merchantable quality and fit for that purpose.

131. Defendants breached its implied warranty because each Defendant's Valsartan product was not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

132. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' Valsartan product they purchased was so inherently flawed, unfit, or unmerchantable as to have essentially zero, significantly diminished, or no intrinsic market value. ☀

☀☀
THIRD CAUSE OF ACTION
FRAUD
(INDIVIDUALLY AND ON BEHALF OF THE CLASS) ☀

133. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

134. Defendants affirmatively misrepresented material facts including, inter alia, that their Valsartan products were therapeutically equivalent to brand Diovan and/or complied with cGMPs and/or were not adulterated.

135. Defendants failed to disclose material facts to render non-misleading its statements about, inter alia, that their Valsartan products were not therapeutically equivalent to brand Diovan and/or did not comply with cGMPs and/or were adulterated.

136. Defendants' actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendants' Valsartan product – product which Defendants knew or should have known was not therapeutically equivalent to brand Diovan and/or did not comply with GMPs

and/or were adulterated. Plaintiffs and other Class Members would not have paid some or all of the amounts they paid for Defendants' Valsartan product had they known the truth.

137. Defendants knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

138. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Class members to pay for some or all of the cost of Defendants' Valsartan products.

139. Defendants' misrepresentations and omissions were material.

140. To the extent applicable, Defendants intended their misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for Defendants' Valsartan product.

141. But for these misrepresentations and omissions, Plaintiffs and other Class Members would have not have paid for Defendants' Valsartan product.

142. To the extent applicable, Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated, to each Class member, including through product labeling and other statements by Defendants. No reasonable consumer would have paid what they did for Defendants' Valsartan product but-for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

143. Plaintiffs and other Class Members were damaged by reason of Defendants' misrepresentations and omissions alleged herein.

FOURTH CAUSE OF ACTION
VIOLATION OF STATE CONSUMER PROTECTION LAWS
(INDIVIDUALLY AND ON BEHALF OF THE CLASS) ☀

144. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth

herein.

145. Defendants have violated the consumer protection statutes as follows:

- a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;
- b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;
- c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;
- d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;
- e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;
- f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;
- g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;
- h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Del. Code § 2511, *et seq.*;
- i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;
- j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;
- k. Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Ga. State 10-1-392, *et seq.*;

- l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;
- m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;
- n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;
- o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;
- p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;
- q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;
- r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;
- s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;
- t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;
- u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;
- v. Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Mich. Stat. § 445.901, *et seq.*;

- w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;
- x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;
- y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;
- z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;
- aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;
- bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;
- cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;
- dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;
- ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;
- ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;
- gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;
- hh. Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Va. Code § 59.1-196, *et seq.*;

- uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;
Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;
- vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;
- ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and
- xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute  for the Commonwealth of Puerto Rico.

146.  Defendants' conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

147.  Each Plaintiff and other Class Member are consumers or persons aggrieved by Defendants' misconduct within the meaning of the above statutes.

148.  To the extent applicable, each Defendants knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances.

149.  As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages in an amount – an ascertainable loss – to be proved at trial.

FIFTH CAUSE OF ACTION
UNJUST ENRICHMENT
(INDIVIDUALLY AND ON BEHALF OF THE CLASS) 

150. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

151. As alleged herein, Defendants were unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for Defendants' Valsartan product.

152. Defendants profited immensely from introducing a carcinogen into the United States for human consumption. On top of that, because Defendants' Valsartan products were adulterated, their distribution and sale in the United States was illegal.

153. Plaintiffs and other Class Members were unjustly deprived of money obtained by Defendants as a result of the improper amounts paid for Defendants' Valsartan product. It would be inequitable and unconscionable for Defendants to retain the profit, benefit, and other compensation obtained from Plaintiffs and other Class Members as a result of their wrongful conduct alleged in this Complaint. ☀

154. Plaintiffs and other Class Members are entitled to seek and do seek restitution from Defendants as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendants by virtue of its wrongful conduct. ☀

SIXTH CAUSE OF ACTION
NEGLIGENCE
(INDIVIDUALLY AND ON BEHALF OF THE CLASS) ☀

155. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

156. Defendants owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its Valsartan product.

157. Defendants owed a duty to Plaintiffs and the Class to ensure that the Valsartan product it sold in the United States was therapeutically equivalent to brand Diovan and/or complied with cGMPs and/or was not adulterated. ☀

158. Defendants owed a duty to care to Plaintiffs and the Class because they were the foreseeable, reasonable, and probable user of Valsartan product and victim of each Defendant's fraudulent and deceptive activities. Defendants knew, or should have known, that its Valsartan product was not therapeutically equivalent to brand Diovan and/or did not comply with cGMPs and/or were adulterated, and each was in the best position to uncover and remedy these shortcomings.

159. Defendants failed to do this. Defendants inadequately oversaw the manufacture and sale of its own Valsartan product. Defendants knew that ignoring the manufacturing issues surrounding its Valsartan product would damage Plaintiffs and the Class and increase its own profits.

160. Defendants maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its Valsartan product complied with cGMPs and/or was not adulterated.

161. Defendants' own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its Valsartan product.

162. Defendants breached the duties owed to Plaintiffs and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiffs and the Class.

163. As a direct and proximate result of each Defendants' negligent conduct, Plaintiffs and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION
NEGLIGENCE PER SE
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

164. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth

herein.

165. Defendants owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its Valsartan product.

166. Defendants owed a duty to Plaintiffs and the Class to ensure that the Valsartan product it sold in the United States was therapeutically equivalent to brand Diovan and/or complied with cGMPs and/or was not adulterated.

167. Defendants owed a duty to Plaintiffs and the Class because each State, territory, and possession has adopted and/or adheres to federal cGMP and adulteration standards.

168. Defendants failed to comply with federal cGMPs and/or federal adulteration standards.

169. As a result of Defendants' failures to do so, each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

170. As a direct and proximate result of each Defendants' negligent conduct, Plaintiffs and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

JURY DEMAND

Plaintiffs respectfully requests a trial by jury on all causes of action so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following judgment:

- A. An Order certifying this Action as a class action;
- B. An Order appointing Plaintiffs as Class Representative, and appointing undersigned counsel as Class Counsel to represent the Class;
- C. A Declaration that Defendants are liable pursuant to each and every one of the above-enumerated causes of action;

D. An Order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendants described herein;

E. Payment to Plaintiffs and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial;

F. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law and/or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

G. An award of statutory penalties to the extent available;

H. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and

I. Such other and further relief as this Court may deem just, equitable, or proper.

Dated: December 10, 2018

RESPECTFULLY SUBMITTED,

/s/

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